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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,688	02/10/2004	Gregory B. Altshuler	105090-0232	3815
21125	7590	12/13/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/776,688	Applicant(s) ALTSHULER ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-34 and 37-47 is/are rejected.
- 7) ☒ Claim(s) 18, 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>012805 020705</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is indefinite due to sufficiently long time not being defined. Further, it is not clear if the time is during a single or multiple treatment cycles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 16, 17, 20-22, 25-29, 40-42 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,056,548 to Neuberger et al. Neuberger et al. teach a laser toothbrush applicator and a method to use the toothbrush providing low power radiation in conjunction with an enhanced dental liquid or paste is described. The method provides a safe hygienic dental treatment that can be practiced by anyone and enhances destruction of oral

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viruses and bacteria. The present invention teaches a method which will have a significant effect on the treatment of all types of oral diseases, inflammations, and infections. A pulsed diode laser as well as a continuous wave diode laser can be used with an enhanced dental liquid or paste for selective bio-stimulation within the oral cavity with little more effort than a conscientious person spends brushing their teeth (Col. 3, lines 12-24). The power of the device is disclosed as less than 10 mW (Col. 4, line 16) with treatment times of 1-3 minutes at a wavelength of 904 nanometers (Col. 1, lines 37-41). The device may also use photosensitizers (drug) and the wavelength is selected based on the specific photosensitizer (Col. 1, lines 60-67) with wavelengths of 670, 780 and 820 nanometers specifically disclosed. Lacking any means for restricting the radiation, the radiation would reach all soft tissue of the oral cavity including facial tissue and the red wavelengths are known to penetrate well. The brushing of teeth is typically done twice a day, thus providing multiple treatments. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Claims 31-34 and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,699,040 to Hahn et al. Hahn et al. teach a method for radiating within an oral cavity (Fig. 2) using a coupling material to maximize the transference of the radiation to tissue (Col. 15, lines 15-25). The material may be a liquid or a gel and may have fluorescent properties (Col. 3, line 5). Any liquid or gel has some penetrating ability.

Regarding claim 34, Hahn et al. teach the use of infrared wavelengths (Col. 14, line 34).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 1 above, and further in view of U.S. Patent 6,026,828 to Altshuler. Neuberger et al. are discussed above, but do not teach lower wavelengths. Altshuler teaches a device for providing radiation to an oral cavity and discloses that it has been found that there is antibacterial and anti-inflammatory action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. In addition the red (630-640 nm) and near IR (830-1300 nm) radiation also provides profilaxis and caries treating influence (Col. 2, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the lower wavelengths as taught by Altshuler in the method of Neuberger et al. as Altshuler specifically teaches the benefits of using such wavelengths in radiation in an oral cavity.

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Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 1 above, and further in view of U.S. Patent 6,135,774 to Hack et al. Neuberger et al. are discussed above, but do not teach the use of diagnostic signals. Hack et al. teach a device for detecting fluorescence from teeth that may be used as a measure of whiteness. One of the disclosed uses of Neuberger et al. is for tooth whitening, so it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the detector as taught by Hack et al. in the method of Neuberger et al. as feedback regarding a whitening procedure.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 20 above, and further in view of U.S. Patent 6,026,828 to Altshuler. Neuberger et al. are discussed above, but do not teach wavelengths below 670 nanometers. Altshuler teaches a device for providing radiation to an oral cavity and discloses that it has been found that there is antibacterial and anti-inflammatory action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. In addition the red (630-640 nm) and near IR (830-1300 nm) radiation also provides profilaxis and caries treating influence (Col. 2, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the lower wavelengths as taught by Altshuler in the method of Neuberger et al. as Altshuler specifically teaches the benefits of using such wavelengths in radiation in an oral cavity.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 1 above, and further in view of U.S. Patent 6,623,513 to Biel. Neuberger et al. are discussed above, but do not teach the systemic introduction of the photosensitizer. Biel teaches photosensitizers for Photodynamic therapy introduced by intravenous injection (col. 1, line 59). It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to inject the photosensitizer as taught by Biel in the method of Neuberger et al. as an alternative means to provide the sensitizer at the treatment site. Such injection is well known in the art.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,548 to Neuberger et al as applied to claim 40 above, and further in view of U.S. Patent 6,623,513 to Biel. Neuberger et al. are discussed above, but do not teach the systemic introduction of the photosensitizer. Biel teaches photosensitizers for Photodynamic therapy introduced by intravenous injection (col. 1, line 59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the photosensitizer as taught by Biel in the method of Neuberger et al. as an alternative means to provide the sensitizer at the treatment site. Such injection is well known in the art.

Allowable Subject Matter

Claims 18, 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

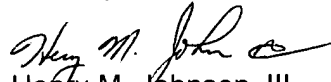
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Patent Examiner
Art Unit 3739